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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,702

07/14/2006

Timothy Joseph Nicholas Carter

1768-138

2537

6449

7590

09/28/2009

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

1425 K STREET, N.W.

SUITE 800

WASHINGTON, DC 20005

EXAMINER

HYUN, PAUL SANG HWA

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

09/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,702	CARTER ET AL.	
	Examiner	Art Unit	
	PAUL S. HYUN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/07/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment filed on July 14, 2006 cancelling claims 1-29 and adding new claims 30-57 has been acknowledged.

The preliminary amendment adding the continuation data of the application has also been acknowledged.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the reagent chamber recited in claims 46 and 47 must be shown or the feature canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **30-34, 37-53, 56 and 57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. (US 5,622,868) in view of Schwabacher et al. (US 7,244,572 B1).

Clarke et al. disclose an analytical device 70 (see Fig. 5). The device comprises a test chamber having entrance 72 for accommodating a cartridge 50. The cartridge 50 comprises a pyroelectric transducer 10 covered by a pair of electrodes 12 and 14 (see Fig. 1). Reagents 62 (e.g. antibodies labeled with dyes, see lines 42-52, col. 4) are adsorbed onto electrode layer 12 wherein each reagent is configured to react with a different antigen of interest. Upon reacting with the antigen of interest, the reagent undergoes a colorimetric change. When the reagent/antigen complex is illuminated by pulses of light (see lines 35-40, col. 2), a detectable signal is produced which is relayed to a processor (see Abstract). The signal is indicative of the identity as well as the concentration of the antigen (see lines 5-6, col. 9). The device disclosed by Clarke et al. differs from the claimed invention in that Clarke et al. do not disclose that the processor is adapted to measure the delay from the time a pulse of radiation from the light source is generated and a signal from the reagent is detected.

Schwabacher et al. disclose an analyzer comprising an array of different probes supported on a substrate. Each probe in the array is configured to react with a specific labeled analyte that generates a signal upon excitation by a light source. The analyzer is configured to measure the time delay between the excitation and the detection of a signal to determine the location of the signal source. The signal location is then used to identify the analyte. In light of the disclosure of Schwabacher et al. and given that the

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device disclosed by Clarke et al. utilizes an array of reagents, it would have been obvious to one of ordinary skill in the art to enable the processor disclosed by Clarke et al. to determine the location of the signal source by measuring the delay between the generation of the excitation source and the detection of a signal. The modification would obviate the need to provide a separate transducer for each reagent (see lines 23-28, col. 6 and Fig. 10).

With respect to claims 37-41, limitation directed towards the time delay only limits the claimed invention so far as to specify the ability of the claimed invention to measure the claimed time delays. That said, it appears that the processor disclosed by Schwabacher et al. is capable of measuring delay having the claimed temporal ranges. The reference discloses that the analyzer is capable of processing a delay as short as 17 microseconds (see lines 28-30, col. 13).

With respect to claims 44 and 45, the claims do not further limit the claimed invention because the claims further limit a feature (i.e. analyte) that is not part of the claimed invention.

With respect to claims 48 and 57, given that the processor disclosed by Schwabacher et al. is capable of processing a new signal every 17 microseconds, it would have been obvious to one of ordinary skill in the art to enable the light source disclosed by Clarke et al. to generate a pulse at a frequency of at least 2 Hz to optimize efficiency.

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Claims **35, 36, 54 and 55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. in view of Schwabacher et al. as applied to claims 30-34, 37-53, 56 and 57, and further in view of Charych et al. (US 6,306,598 B1).

Although Clarke et al. disclose the use of various reagents, the reference does not disclose the use of avidin, biotin or nucleic acid sequences as reagents.

Charych et al. disclose a colorimetric-based analyzer for assaying nucleic acid sequences present in a sample. The analyzer comprises a substrate on which nucleic acid sequences are immobilized. The immobilized nucleic acid sequences are intended to bind complementary nucleic acid sequences. Upon binding, a colorimetric change occurs, enabling detection (see line 11, col. 21). The reference also discloses the use of avidin/biotin conjugate to bind an analyte of interest (see line 31, col. 9). In light of the disclosure of Charych et al., it would have been obvious to one of ordinary skill in the art to use nucleic acid sequences as the reagent in the modified Clarke et al. device so that nucleic acids can be assayed. Likewise, it would have been obvious to one of ordinary skill in the art to utilize biotin/avidin conjugate to bind an analyte of interest.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797